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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,135	12/31/2003	Steven Bernard	3659-78	6862

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EXAMINER
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KIM, SUN U

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application N .	Applicant(s)	
	10/748,135	BERNARD ET AL.	
	Examiner	Art Unit	
	John Kim	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2006 and 29 June 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Pri ority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/29/06</u> . | 6) <input type="checkbox"/> Other: _____  |

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1. Claim 7 is objected to because of the following informalities: “the stem outside diameter is substantially narrower than the disk of potting material” on lines 5-6 should be corrected to ““the stem outside diameter is substantially narrower than an outside diameter of the disk of potting material”. Appropriate correction is required.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Recitation of “a cap side surface substantially perpendicular to the stem of fibers” in claim 7 is not described in the specification. Rather, a cap side surface is substantially perpendicular to the end surface of the end section. Recitation of “an outside diameter of an entirety of the end section is substantially narrower than an outside diameter of the bundle of hollow fibers inward of the end section” in claim 1 is not described in the specification. Rather, an outside diameter of an entirety of the end section is greater than an outside diameter of the bundle of hollow fibers inward of the end section. Recitation of “the stem outside diameter is substantially narrower than an outside diameter of the bundle of hollow fibers inward of the end section” in claim 7 is not described in the specification. Rather, the stem outside diameter is greater than an outside diameter of the bundle of hollow fibers inward of the end section. Inward means “toward the inside, interior, or center”. In this case, the diameter of hollow fiber bundle is

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always smaller than the outside diameter of the end section or the stem outside diameter because a bundle of hollow fibers having an end section is encased in a potting material.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-15 are indefinite for failing to particularly point out what direction is inward of the end section. For examination purpose, inward of the end section is considered inward vertical direction along the bundle of hollow fibers.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-2 and 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Geel et al (US Pat. No. 4,414,110). Geel et al teach a filter comprising a bundle (26) of hollow fibers (27) arranged in a tubular housing and having an end section (30) encased in a potting material and an end surface (34) with open ends of the fibers throughout the end face (34) and a side surface generally perpendicular to the end surface (34) wherein an outside diameter of an entirety of the end section (30) is substantially narrower than an outside diameter of the bundle (26) of hollow

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fibers (27) inward of the end section (30) and a filter header cap (44) having an inlet (16) connectable to a blood line and an open end sealed around a side surface of the end section of the bundle (26) of hollow fibers (27) wherein the open end of the cap includes a tapered cap side surface (80) generally parallel to the side surface of the end section (30) of the potting material wherein the end section (30) abuts a cap side surface (80) and the side surface of the end section (30) and the cap side surface (80) are tapered along the abutment and a housing including chamber (12, 14) and a first end to receive the filter header cap (44) and a second end having an outlet connectable to a blood line (see figures 1-3, 5-7; col. 4, lines 26-62; col. 5, lines 4-25; col. 6, lines 52-68; col. 7, line 53 – col. 8, line 40)(claim 1). Regarding claim 2, Geel et al show that the inlet (16) is coaxial with the filter (see figure 5). Regarding claim 5, Geel et al show that the end section is an end of a stem (30) of the bundle extending outwardly from a disk of the potting material (32) (see figure 5; col. 5, lines 3-10). Regarding claim 6, Geel et al show that the disk of the potting material (30) is fitted into the cap (44) and the cap (44) is mounted on the cylindrical tube housing the bundle (26) (see figures 3, 5).

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geel et al. Geel et al teach the filter as described in above paragraph 7. Geel et al shows that rim area of the potting material is devoid of the open ends of the fibers (see figure 3). Claims 3-4 essentially differ from the filter of Geel et al in reciting that the end surface includes a rim area of potting

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material having a width no greater than on average than 0.508 mm. The rim area of the potting material of Geel et al provides a wall (30) surrounding the bundle of hollow fibers fitted in a housing (see figure 3; col. 5, lines 3-25). It would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the width of wall i.e. rim area of the potting material in the filter of Geel et al to be supported in a housing, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

10. Applicant's arguments with respect to claims 1-15 have been considered but are moot in view of the new ground(s) of rejection.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is 571-272-1142. The examiner can normally be reached on Monday-Friday 7 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
**John Kim**  
**Primary Examiner**  
**Art Unit 1723**

JK

August 22, 2006